

American National Standard

ANSI/AAMI EC38:2007



Medical electrical equipment – Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems

Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

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All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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Medical electrical equipment – Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems

Developed by
Association for the Advancement of Medical Instrumentation

Approved 10 December 2007 by
American National Standards Institute, Inc.

Abstract: To establish particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems that provide continuous recording and analysis of ECG.

Keywords: ambulatory electrocardiographic system, ambulatory recorder, electrocardiogram, electrode, continuous recorder

AAMI Standard

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Published by

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Road, Suite 220
Arlington, VA 22201-4795
www.aami.org

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Printed in the United States of America

ISBN 1-57020-312-1

Contents

	Page
Glossary of equivalent standards.....	vii
Committee representation	ix
Background of ANSI/AAMI adoption of IEC 60601-2-47:2001	x
AAMI Deviations to IEC 60601-2-47:2001	xi
Foreword	xxvii
Introduction.....	xxix

SECTION ONE – GENERAL

1	Scope and object	1
1.1	Scope	1
1.2	Object.....	1
1.3	Particular Standards.....	1
1.5	Collateral Standards.....	2
*2	Terminology and definitions.....	2
5	Classification	3
6	Indentation, marking and documentation	3
6.1	Marking on the outside of EQUIPMENT or EQUIPMENT parts	4
6.8.2	Instructions for use	4

SECTION TWO – ENVIRONMENTAL CONDITIONS

*10	Environmental conditions	5
10.2.1	Environment	5

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

20	Dielectric strength.....	5
20.2	Particular requirements for EQUIPMENT with an APPLIED PART.....	5
20.3	Values of test voltages	5

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

21	Mechanical strength	6
----	---------------------------	---

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

*36	ELECTROMAGNETIC COMPATIBILITY.....	7
36.201	Emissions	7
36.201.1	Radio frequency (RF) emissions.....	7
36.202	Immunity.....	7
*36.202.1	Electrostatic discharge	7
*36.202.2	Radiated radio-frequency electromagnetic fields	7
36.202.6	Magnetic fields.....	8

SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

50	Accuracy of operating data.....	8
*	50.101 Automated analysis.....	9
*	50.101.1 Standard databases to be used to evaluate automated analyses.....	9
*	50.101.2 Performance reporting requirements	9
*	50.101.3 Physician report - minimum requirements	9
51	Protection against hazardous output.....	10
*	51.5 Incorrect output.....	10
*	51.5.1 Input dynamic range.....	10
*	51.5.2 Input impedance	11
*	51.5.3 Common mode rejection.....	11
*	51.5.4 Gain accuracy	12
*	51.5.5 Gain stability	12
*	51.5.6 Amplitude calibration.....	12
*	51.5.7 System noise	13
*	51.5.8 Multichannel crosstalk.....	13
*	51.5.9 Frequency response.....	13
*	51.5.10 Minimum feature size	14
*	51.5.11 Function in the presence of pacemaker pulse	15
*	51.5.12 Timing accuracy	16
*	51.5.13 Hard copy grid standard	16
*	51.5.14 Gain settings and switching	17
*	51.5.15 Temporal alignment.....	17
	51.5.16 Special considerations for high speed superimposition display (optional)...	17
	51.5.17 Lead Definitions	18
	51.5.18 Baseline stability	19
	51.5.19 Patient event marks	19
	51.5.20 Full disclosure (miniature displays).....	19

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

*56	Components and general assembly	19
*	56.7 Batteries	19
*	56.7.101 Monitoring time and retention of data	20

Annexes

Appendix L—References – Publications mentioned in this Standard.....	25
Annex AA (informative)—Guidance and rationale	26

Tables

Table 101—Lead color codes	4
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Figures

Figure 101—Test set-up for conductive emission test according to 36.201.1	20
Figure 102—Test set-up for radiated emission and radiated immunity test according to 36.201.1 and 36.202.2	21
Figure 103—Test signal for input dynamic range test according to 51.5.1.....	22
Figure 104—General test circuit for 51.5.....	22
Figure 105—Test circuit for common mode rejection according to 51.5.3.....	23
Figure 106—Test circuit for pacemaker pulse tolerance according to 51.5.11.....	24

Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1:2005	ANSI/AAMI ES60601-1:2005	Major technical variations
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007	Identical
IEC 60601-2-2:2006	ANSI/AAMI/IEC 60601-2-2:2006	Identical
IEC 60601-2-4:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:1990 and Amendment 1:1996	ANSI/AAMI I136:2004	Major technical variations
IEC 60601-2-20:1990 and Amendment 1:1996	ANSI/AAMI I151:2004	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 and Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004	Major technical variations
IEC 60601-2-47:2001	ANSI/AAMI EC38:2007	Major technical variations
IEC 60601-2-50:2001	ANSI/AAMI/IEC 60601-2-50:2006	Identical
IEC/TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 8637:2004	ANSI/AAMI RD16:2007	Major technical variations
ISO 8638:2004	ANSI/AAMI RD17:2007	Major technical variations
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002 and Amendment 1:2006	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999/(R)2005	Identical
ISO 10993-10:2002 and Amendment 1:2006	ANSI/AAMI BE78:2002 ANSI/AAMI BE78:2002/A1:2006	Minor technical variations Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006	Identical
ISO 10993-12:2007	ANSI/AAMI/ISO 10993-12:2007	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001/(R)2006	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000/(R)2006	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical

International designation	U.S. designation	Equivalency
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006	Identical
ISO 11137-2:2006 (2006-08-01 corrected version)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006	Identical
ISO 11138-1: 2006	ANSI/AAMI/ISO 11138-1:2006	Identical
ISO 11138-2: 2006	ANSI/AAMI/ISO 11138-2:2006	Identical
ISO 11138-3: 2006	ANSI/AAMI/ISO 11138-3:2006	Identical
ISO 11138-4: 2006	ANSI/AAMI/ISO 11138-4:2006	Identical
ISO 11138-5: 2006	ANSI/AAMI/ISO 11138-5:2006	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005	Identical
ISO 11140-3:2007	ANSI/AAMI/ISO 11140-3:2007	Identical
ISO 11140-4:2007	ANSI/AAMI/ISO 11140-4:2007	Identical
ISO 11140-5:2007	ANSI/AAMI/ISO 11140-5:2007	Identical
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006	Identical
ISO 11737-1: 2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 11737-3:2004	ANSI/AAMI/ISO 11737-3:2004	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161:2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2007	ANSI/AAMI/ISO 14971:2007	Identical
ISO 15223-1:2007	ANSI/AAMI/ISO 15223-1:2007	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO 15882:2003	ANSI/AAMI/ISO 15882:2003	Identical
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2005	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006	Identical
ISO/TS 19218:2005	ANSI/AAMI/ISO 19218:2005	Identical
ISO 22442-1:2007	ANSI/AAMI/ISO 22442-1:2007	Identical
ISO 22442-2:2007	ANSI/AAMI/ISO 22442-2:2007	Identical
ISO 22442-3:2007	ANSI/AAMI/ISO 22442-3:2007	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003 and A1:2005	Identical
ISO 81060-1:2007	ANSI/AAMI/ISO 81060-1:2007	Identical

Committee representation

Association for the Advancement of Medical Instrumentation Electrocardiograph (ECG) Committee

This standard was developed by the ECG/Ambulatory Electrocardiograph Working Group of the Electrocardiograph Committee of the Association for the Advancement of Medical Instrumentation. Committee approval of the standard does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI Electrocardiograph Committee** had the following members:

Cochairs: Carole Carey
Carl A. Pantiskas
Members: Robert E. Bruce, Medcomp, Inc.
Carole Carey, U.S. Food and Drug Administration
Arthur R. Eddy, Jr., ConMed Corp.
George Moody, Massachusetts Institute of Technology
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Stephen A. Marinello, Draeger Medical
Mary Schneider, G.E. Healthcare
John Wang, Philips Medical Systems

NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Background of ANSI/AAMI adoption of IEC 60601-2-47:2001

This standard was developed by the ECG/Ambulatory Electrocardiograph Working Group of the AAMI Electrocardiograph (ECG) Committee. The objective of this standard is to provide minimum labeling, performance, and safety requirements that will help ensure a reasonable level of clinical efficacy and patient safety in the use of ambulatory electrocardiographs (ECGs).

This standard is written primarily for manufacturers of ambulatory monitoring systems to give them clear labeling, design, performance, and test specifications which, if met, should promote patient safety and diagnostic quality of the results. The standard will also be useful to ambulatory monitoring equipment users because knowledge of the standard will give the user a more precise understanding of the characteristics and limitations of the equipment; such understanding is conducive to a safer and more efficacious use of the device.

This is a revision of ANSI/AAMI EC38:1998, *Ambulatory electrocardiographs*. During the course of revision, the AAMI ECG/Ambulatory Electrocardiograph Working Group decided to adopt IEC 60601-2-47, *Medical electrical equipment – Part 2 – 47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems*, which is based in large part on the AAMI standard noted above. The working group also decided to include some requirements and informative text which apply only to the AAMI standard and to refer to ANSI/AAMI EC57:1998(R)2003 as a new normative reference. Thus, EC57's more comprehensive set of reporting requirements are used instead of those found in the IEC standard. These include areas which the IEC standard does not address.

IEC 60601-2-47:2001 was developed by IEC Subcommittee (SC) 62D, Electromedical Equipment, which is administered by AAMI on behalf of the International Electrotechnical Commission (IEC), a worldwide organization for standardization. As previously noted, AAMI standards served as the basis of the international standard. In addition, the AAMI ECG/Ambulatory Electrocardiograph Working Group, working as the U.S. Technical Advisory sub-Group for IEC/SC 62D/WG1 (now IEC/SC 62D/MT22, Electromedical diagnostic and patient monitoring equipment), was responsible for developing U.S. consensus on the international standard and otherwise participated in the drafting of that document.

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data comes to light.

This standard reflects the conscientious efforts of concerned health care professionals and medical device manufacturers to develop a standard for those performance levels that can be reasonably achieved at this time.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—This foreword does not contain provisions of the American National Standard, *Medical electrical equipment – Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems* (ANSI/AAMI EC38:2007), but it does provide important information about the development and intended use of the document.

AAMI Deviations to IEC 60601-2-47:2001

The U.S. deviations to IEC 60601-2-47:2001 that appear in ANSI/AAMI EC38:2007 are:

SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

***50.101.1 Standard databases to be used to evaluate automated analyses**

IEC Requirement

Four standard databases are available from three sources for evaluating ambulatory ECG analyzers and have been widely used for that purpose.

- AHA database: The American Heart Association Database for Evaluation of Ventricular Arrhythmia Detectors (80 records, 30 min each);
- MIT database: The Massachusetts Institute of Technology–Beth Israel Hospital Arrhythmia Database (48 records, 30 min each);
- NST database: The Noise Stress Test Database (12 records, 30 min each; supplied with the MIT database);
- CU database: The Creighton University Sustained Ventricular Arrhythmia Database (35 records, 8 min each; supplied with the MIT database).

The first three databases consist of digitized excerpts of two-channel Holter recordings, with each beat labeled. The CU database contains digitized single-channel ECG recordings with rhythm changes labeled. This is a complete list of those databases that are both adequate as a basis for evaluation and generally available at present.

Replaced by ANSI/AAMI Requirement

See ANSI/AAMI EC57:1998/(R)2003.

***50.101.2 Performance reporting requirements**

IEC Requirement

50.101.2.1 Standard databases to be used for the performance test

The accuracy of QRS detection shall be tested using the AHA database, the MIT database, and the NST database.

The accuracy of ventricular ectopic beat (VEB) detection shall be tested using the AHA database, the MIT database, and the NST database.

If the EQUIPMENT is claimed to detect ventricular flutter or fibrillation (VF), its ability to do so shall be tested using the CU database, the AHA database and the MIT database.

If the EQUIPMENT is claimed to detect supraventricular ectopic beats (SVEBs) or atrial flutter or fibrillation (AF), its ability to do so shall be tested using the MIT database and the NST database.

50.101.2.2 Record-by-record results

For each record, the following statistics shall be reported:

- QRS sensitivity and positive predictivity;

- VEB sensitivity and positive predictivity.

For each record, any of the following statistics that are relevant to the EQUIPMENT's claimed capabilities shall also be reported:

- VF episode sensitivity and positive predictivity;
- SVEB sensitivity and positive predictivity;
- AF episode sensitivity and positive predictivity.

50.101.2.3 Statistics

Based on the record-by-record reports required by 50.101.2.2, gross statistics summarizing the performance of the EQUIPMENT under test on each of the databases used for testing shall be reported in tabular format as shown in table 102 and 103. Symbols and abbreviations used in these tables are:

- G gross statistic (calculated for the entire database)
- +P positive predictivity
- R required (if the EQUIPMENT is claimed to detect the abnormality, the statistic shall be reported)
- Se sensitivity
- VEB ventricular ectopic beat
- SVEB supraventricular ectopic beat
- TP true positive
- TN true negative
- FP false positive
- FN false negative

Table 102 – Reporting requirements for standard analyzer outputs

Statistic	AHA DB	MIT DB	NST DB	CU DB
QRS Se (G)	R	R	R	–
QRS +P (G)	R	R	R	–
VEB Se (G)	R	R	R	–
VEB +P (G)	R	R	R	–
VEB Couplets Se (G)	R	R	–	R
VEB Couplets +P (G)	R	R	–	R
VEB Short Runs Se (G)	R	R	–	R
VEB Short Runs +P (G)	R	R	–	R
VEB Long Runs Se (G)	R	R	–	R
VEB Long Runs +P (G)	R	R	–	R

Table 103 – Reporting requirements for optional analyzer outputs

Statistic	AHA DB	MIT DB	NST DB	CU DB
VF Episode Se (G)	R	R	–	R
VF Episode +P (G)	R	R	–	R
SVEB Se (G)	–	R	R	–
SVEB +P (G)	–	R	R	–

50.101.2.4 Test methods

(NOTE For maximum legibility the text in subclauses a) to d) is not italicized.)

a) Use of the standard databases for test

Each record shall be supplied to the EQUIPMENT continuously from the beginning to the end (that is, without rewinding or 'fast forwarding'). This requirement applies only to the manner in which the evaluator presents ECG samples to the EQUIPMENT under test and in no way is to be construed as a restriction on the manner in which the EQUIPMENT normally performs its analysis.

If the digitized ECG signals from the database records are pre-processed in any way before presenting them as input to the equipment under test, the pre-processing shall be disclosed in sufficient detail to permit a third party to reproduce the test. Pre-processing includes, but is not limited to:

- resampling (i.e., conversion to a sampling rate different from that used in the standard database files);
- reformatting (i.e., conversion of byte order, sample precision or numeric coding);
- rescaling (altering the signal amplitude, i.e, changing the gain);
- filtering performed by software or hardware not employed in the normal operating mode of the equipment under test;
- conversion from digital to analogue signals.

If the evaluation of the equipment under test is performed using signals converted into analogue form and supplied to the normal analogue inputs of the equipment, the equipment's automatic gain control (AGC) will be allowed to adjust the gain automatically. If the evaluation is performed using digital data and the AGC is not digital but part of the analogue front end of the equipment, the equipment may simulate its AGC capabilities by an alternative method. This alternative method allows the 'test mode' that generates the 'test annotations' to emit an announcement that a 'gain adjustment' would be required prior to proceeding with analyzing the ECG for each patient record. This announcement should instruct the evaluator to adjust the gain of the ECG for either one or both of the ECG channels. The evaluator shall then run the 'xform' (or equivalent) program to adjust the ECG's gain based on the instructions provided by the program. This process shall be repeated until 'no gain change' is announced and the equipment under test shall then automatically proceed with the ECG analysis.

Beat-by-beat comparisons, following the protocol described in 50.101.2.4 c), shall be used to derive QRS Se, QRS +P, VEB Se, VEB +P, and (where applicable) SVEB Se and SVEB +P. The protocol described in 50.101.2.4 d) shall be used to derive VF and AF episode Se and +P, where applicable.

b) Use of annotation files

The test protocols described in 50.101.2.4 c) through 50.101.2.4 d) require that, for each record, the output of the equipment has been recorded in an annotation file (the test annotation file) in the same format as the reference annotation file for that record. The equipment need not produce this file directly. Any automated procedure for doing so is acceptable as long as it is disclosed. To perform the comparison between the test annotation files and the reference annotation files, the programs supplied on the MIT-BIH Arrhythmia Database CD-ROM (programs 'bxb', 'rxr', 'epic', 'mxm') or later versions released by MIT or programs with equivalent function and output shall be used. A manufacturer using programs other than the ones released by MIT shall show the equivalence of his programs. The reference annotation files distributed with the databases and used as input to these programs may not be altered in any way, except that (where applicable) corrected reference annotation files obtained from the database suppliers may be substituted for those originally distributed with the databases.

Within annotation files, beat labels are defined as follows:

- N: any beat that does not fall into the S, V, F, or Q categories described below (normal or bundle branch block beat);
- S: supraventricular ectopic beat (SVEB): an atrial or nodal (functional) premature or escape beat or an aberrant atrial premature beat;
- V: ventricular ectopic beat (VEB): a ventricular premature beat, an "R-on-T" ventricular premature beat or a ventricular escape beat;
- F: fusion of a ventricular and a normal beat;
- Q: paced beat, fusion of a paced and normal beat or a beat that cannot be classified.

Other labels are needed to facilitate the beat-by-beat comparison process defined in 50.102.2.4 c):

- U: label that marks a segment of unreadable data.

U labels appear in the database where beats cannot be located because of excessive noise or signal loss in both channels.

In the MIT database, a pair of U labels marks the beginning and end of each unreadable segment.

In the AHA database, a single U label marks the (approximate) centre of each unreadable segment, which is assumed for testing purposes to begin 150 ms after the previous beat label, and to end 150 ms before the following beat label.

In order to mark segments during which an equipment's analysis is suspended (shut down) because of excessive noise or signal loss, or for any other reason, equipment may also generate U labels. Beat labels are never paired with U labels during beat-by-beat comparisons.

Extra beats are sometimes detected (false positive 'QRS') and true beats are sometimes missed (false negative QRS). In order to perform beat-by-beat comparisons, pseudo-beat labels are added to those in the reference and test annotation files, to preserve a one-to-one correspondence between beat labels. They represent the absence of a beat label. There are two types:

- X: a pseudo-beat label generated during a segment marked as unreadable;
- O: a pseudo-beat label generated at any other time.

In beat-by-beat comparisons, all beat labels are paired up. If either the reference or the test annotation file contains an extra beat label that has no match in the other file, the

appropriate O or X label is paired with the extra label. This corresponds to a QRS detection error – either a false detection (if the extra label is in the test annotation file) or a missed beat (if it is in the reference annotation file). All such beat label pairs are counted, including those that involve O or X labels. O and X labels are not used in run-by-run comparisons (50.101.2.4 c)), or for VF and AF comparisons (50.101.2.4 d)), since it is not necessary in these instances to pair individual beat labels.

Rhythm labels mark segments of ventricular flutter or fibrillation (VF) in the AHA and MIT databases:

- [: beginning of VF
-] : end of VF

Beat labeling is discontinued between '[' and ']' labels. VF segments are excluded from beat-by-beat comparisons. Additional rhythm labels mark changes in rhythm in the MIT database. Those which mark segments of atrial flutter or fibrillation (AF, see the documentation which accompanies each database) are used for evaluation of AF detection, others are ignored. Beat labels are never paired with rhythm labels.

c) Beat-by-beat comparison

During a beat-by-beat comparison, reference beat labels and equipment beat labels are matched up in pairs. To be considered a match, the absolute value of the difference between the equipment's estimate of the time of occurrence of a beat and the time as recorded in the reference annotation file shall not exceed 150 ms. If matching does not occur within this window, the candidate beat is considered to have been missed or to be an extra detection. The end product of a beat-by-beat comparison is a matrix in which each element is a correct count of the number of beat label pairs of the appropriate type:

Table 104 – Beat-by-beat matrix

Reference label	Algorithm label						
	n	s	v	f	q	o	x
N	Nn	Ns	Nv	Nf	Nq	No	Nx
S	Sn	Ss	Sv	Sf	Sq	So	Sx
V	Vn	Vs	Vv	Vf	Vq	Vo	Vx
F	Fn	Fs	Fv	Ff	Fq	Fo	Fx
Q	Qn	Qs	Qv	Qf	Qq	Qo	Qx
O	On	Os	Ov	Of	Oq		
X	Xn	Xs	Xv	Xf	Xq		

The beat-by-beat comparison is performed according to the following method:

- 1) Set the variable T to the time of the first reference beat label after the end of the learning period and set the variable t to the time of the first test beat label after the end of the learning period. Set all elements of the matrix to zero.

If T is within 150 ms of the beginning of the test period, it is possible that a matching test beat label may be placed before the beginning of the test period. If this occurs, it is counted as a match (t is set to the time of the matching test beat label before going on to step 2). On the other hand, if t is within 150 ms of the beginning of the test period and there is no matching reference beat label after the beginning of the test period, the test annotation at t is not counted (t is set to the time of the next test beat label before going on to step 2).

2) One of the following cases shall apply:

- a) If t precedes T , set t' to the time of the next test beat label (or to a time beyond the end of the record if there are no more test beat labels). There are now two possibilities:
 - (i) If T is closer to t than to t' , and t is within 150 ms (the match window) of T , the beat labels at T and t are paired. The variable T is reset to the time of the next reference beat label.
 - (ii) Otherwise, the test beat label at t is an extra detection. The extra label is paired with an O or X 'pseudo-beat' label. The variable t is reset to the value of t' .
- b) If t does not precede T , set T' to the time of the next reference beat label (or to a time beyond the end of the record if there are no more reference beat labels). There are again two possibilities:
 - (i) If t is closer to T than to T' , and t is within 150 ms of T , the beat labels at T and t are paired. The variable t is reset to the time of the next test beat label.
 - (ii) Otherwise, the equipment has missed the beat at T . The extra reference beat label is paired with an O or X "pseudo-beat" label. The variable T is reset to the value of T' .
- c) The matrix element corresponding to the beat label pair which was generated in step b) is incremented.
- d) Steps b) and c) are repeated until both t and T are set to times beyond the end of the record.

During the derivation of the matrix, the procedure has to keep track of segments that have been marked as unreadable or as VF in either the reference or the test annotation file. During unreadable segments, pseudo-beat labels are X; at all other times, pseudo-beat labels are O. Test beat labels generated during true VF segments are not counted for these purposes. Reference beat labels present during equipment-marked VF segments are paired with O pseudo-beat labels and counted like all other missed beats. In principle, an unreadable segment or a VF segment may begin during the learning period, this possibility shall be taken into account by software designed to perform beat-by-beat comparisons.

The results of beat-by-beat comparisons are used to derive QRS sensitivity and positive predictivity:

$$\begin{aligned}
 QTP &= Nn + Ns + Nv + Nf + Nq + & QFN &= No + Nx \\
 &Sn + Ss + Sv + Sf + Sq + & &So + Sx + \\
 &Vn + Vs + Vv + Vf + Vq + & &Vo + Vx -+ \\
 &Fn + Fs + Fv + Ff + Fq + & &Fo + Fx + \\
 &Qn + Qs + Qv + Qf + Qq & &Qo + Qx \\
 QFP &= On + Os + Ov + Of + Oq + Xn + Xs + Xv + Xf + Xq \\
 QRS\ Se &= QTP/(QTP + QFN) & QRS\ +P &= QTP/(QTP + QFP)
 \end{aligned}$$

The results of beat-by-beat comparisons are used to derive VEB sensitivity and positive predictivity:

$$VTP = V_v$$

$$VFN = V_n + V_s + V_f + V_q + V_o + V_x$$

$$VFP = N_v + S_v + O_v + X_v$$

$$VEB\ Se = VTP / (VTP + VFN)$$

$$VEB + P = VTP / (VTP + VFP)$$

Note that VTP and VFP do not include F_v or Q_v , thus a detector is neither penalized nor rewarded for its treatment of ventricular fusion beats and ambiguous beats.

SVEB sensitivity and positive predictivity are similarly defined:

$$SVTP = S_s$$

$$SVFN = S_n + S_v + S_f + S_q + S_o + S_x$$

$$SVFP = N_s + V_s + F_s + O_s + X_s$$

$$SVEB\ Se = SVTP / (SVTP + SVFN)$$

$$SVEB + P = SVTP / (SVTP + SVFP)$$

Again, note that Q_s is excluded from SVTP and SVFP, so that a detector's treatment of ambiguous beats does not influence its measured SVEB detection performance.

d) VF and AF comparisons

For equipment which is claimed to detect VF, a VF comparison shall be performed. This test requires the production of an annotation file based on the equipment's outputs, containing (at a minimum) the times when the equipment has determined that episodes of VF have begun or ended. Overlap exists during any interval in which both the reference and algorithm annotations indicate that VF is in progress. Each reference episode for which overlap exists is counted as a true positive for purposes of determining VF episode sensitivity; any other reference episodes are counted as false negatives. Similarly, each algorithm-marked episode for which overlap exists is counted as a true positive for purposes of determining VF episode positive predictivity, any other algorithm-marked episodes are counted as false positives.

For equipment which is claimed to detect AF, an AF comparison shall be performed. This test is performed in the same manner as the VF comparison with the substitution of 'AF' for each occurrence of 'VF' in the description above. Segments labeled as atrial flutter in the reference annotation files shall be excluded from this comparison.

From the counts of true positives, false negatives and false positives derived according to the above-mentioned methods, VF and AF episode sensitivity and positive predictivity are derived in the usual way.

Replaced by ANSI/AAMI Requirement

See ANSI/AAMI EC57:1998/(R)2003.

***51.5.9 Frequency response**

IEC Requirement

The EQUIPMENT shall meet the following requirements:

- a) Response of a RECORDER to a 3 mV 100 ms rectangular pulse shall not show a baseline amplitude displacement after the pulse of more than 0.1 mV referred to the baseline before the pulse. The slope outside the pulse shall be less than 0.3 mV/s. The leading edge overshoot shall be less than 10 %.

and either

- b) The amplitude response to sinusoidal signals within the frequency range 0.67 Hz to 40 Hz shall be between 140 % and 70 % (+3 dB to -3 dB) of the response at 5 Hz.

If the manufacturer claims ST segment measurement capability for the EQUIPMENT, lower cut-off frequency shall be 0.05 Hz for a first-order high-pass filter or its functional equivalent.

If the manufacturer claims that the EQUIPMENT is capable of recording ECGs from infants weighing less than 10 kg, the upper cut-off frequency shall be at least 55 Hz.

or

- c) Responses to all pulses of a 1.5 mV, 40 ms triangular pulse train, which simulates a series of narrow R-waves, shall be within 60 % to 110 % of the response to a train of 1.5 mV, 200 ms triangular pulses.

If the manufacturer claims that the EQUIPMENT is capable of recording ECGs from infants weighing less than 10 kg, the response to the 1.5 mV $\times$ 40 ms triangular wave shall be within 80 % to 110 % of the 1.5 mV $\times$ 200 ms triangular wave.

Compliance is checked by the following tests:

The system input is at the PATIENT ELECTRODE; the output is measured on the system's hard copy ECG record.

- a) *Record at least 20 s of zero volt baseline, and then a single 3 mV 100 ms rectangular pulse. Continue recording for at least another 20 s of zero volt baseline.*
- b) *With the test set-up of figure 104, record for at least 5 s a 2 mV p-v sinusoidal signal at 0.67 Hz. Repeat this for 1 Hz, 2 Hz, 5 Hz, 10 Hz, 20 Hz and 40 Hz.*

If the manufacturer claims ST segment measurement capability for the EQUIPMENT, replace in the above series of tests the lower test frequency of 0.67 Hz by 0.05 Hz or its functional equivalent.

If the manufacturer claims that the EQUIPMENT is capable of recording ECGs from infants weighing less than 10 kg, replace in the above series of tests the upper test frequency of 40 Hz by 55 Hz.

- c) *Record for at least 5 s a train of triangular 1.5 mV, 200 ms base width pulses with a repetition rate of 1/s. Then adjust the base width of the triangular pulses to 40 ms. Record during 2 min while slowly changing the repetition rate from 60/min to 70/min in order to ensure that the full range of amplitude variability resulting from sample points missing the peak of the pulse will be obtained.*

Verify the following measures on the hard copy record:

- a) *The output baseline following the 3 mV rectangular pulse is displaced no more than 0,1 mV from the baseline preceding the pulse. The slope outside the region of the pulse does not exceed 0.3 mV/s.*
- b) *The p-v amplitude responses at the frequencies of 0.67 Hz, 1 Hz, 2 Hz, 10 Hz, 20 Hz, 40 Hz are between 70 % and 140 % of the response at 5 Hz.*

If the manufacturer claims ST segment measurement capability for the EQUIPMENT, replace the lower test frequency of 0.67 Hz by 0.05 Hz or its functional equivalent.

If the manufacturer claims that the EQUIPMENT is capable of recording ECGs from infants weighing less than 10 kg, replace the upper test frequency of 40 Hz by 55 Hz.

- c) *The lowest peak-to base amplitude of the 1.5 mV, 40 ms base width triangle pulse train is no less than 60 % of the highest peak-to base amplitude of the 1.5 mV 200 ms base width triangle pulse train.*

If the manufacturer claims that the EQUIPMENT is capable of recording ECGs from infants weighing less than 10 kg, the lowest peak-to base amplitude of the 1.5 mV, 40 ms base width triangle pulse train is no less than 80 % of the highest peak-to-base amplitude of the 1.5 mV 200 ms base width triangle pulse train.

Replaced by ANSI/AAMI Requirement

The overall system frequency response shall meet the specifications described. The input of the system is at the PATIENT ELECTRODES; the output of the system is measured on the system's hard copy ECG record. If special filtering compensation circuits are used in the recorder and/or the reproducer, they shall be disclosed.

a) Response to a 3 mV, 100 ms rectangular pulse shall meet the following criteria.

- 1.) Amplitude displacement of the baseline shall not be greater than 0.1 mV from onset to end in devices claiming ST measurement capabilities or 1.0 mV in devices not claiming ST measurement capabilities.
- 2.) The slope everywhere outside the rectangular pulse shall be less than 0.30 mV/s in devices claiming ST measurement capabilities or 2.0 mV/s in devices not claiming ST measurement capabilities.
- 3.) The leading edge overshoot shall be less than 10%.

b) Amplitude response to sinusoidal signals within the frequency range of 0.67 Hz to 40 Hz shall be between 112% and 71% (+1.0 to -3.0 dB) of the response at 5 Hz with a tolerance of $\pm 5\%$.

And

c) Responses to all pulses of a 1.5 mV, 40 ms triangular pulse train, which simulates a series of narrow R-waves, shall be within 60% to 110% of the response to a train of 1.5 mV, 200 ms triangular pulses.

If the manufacturer claims that the EQUIPMENT is capable of recording ECGs from infants weighing less than 10 kg, the response to the 1.5 mV, 40 ms triangular wave shall be within 80% to 110% of the 1.5 mV, 200 ms triangular wave.

Compliance is checked by the following tests:

The system input is at the PATIENT ELECTRODE; the output is measured on the system's hard copy ECG record.

- a) *Record at least 20 s of zero volt baseline, and then a single 3 mV 100 ms rectangular pulse. Continue recording for at least another 20 s of zero volt baseline.*
- b) *With the test set-up of figure 104, record for at least 5 s a 2 mV p-v sinusoidal signal at 0.67 Hz. Repeat this for 1 Hz, 2 Hz, 5 Hz, 10 Hz, 20 Hz and 40 Hz.*

If the manufacturer claims that the EQUIPMENT is capable of recording ECGs from infants weighing less than 10 kg, replace in the above series of tests the upper test frequency of 40 Hz by 55 Hz.

- c) *Record for at least 5 s a train of triangular 1.5 mV, 200 ms base width pulses with a repetition rate of 1/s. Then adjust the base width of the triangular pulses to 40 ms. Record during 2 min while slowly changing the repetition rate from 60/min to 70/min in order to ensure that the full range of amplitude variability resulting from sample points missing the peak of the pulse will be obtained.*

Verify the following measures on the hard copy record:

- a) *The output baseline following the 3 mV rectangular pulse is displaced no more than 0.1 mV from the baseline preceding the pulse. The slope outside the region of the pulse does not exceed 0.3 mV/s.*
- b) *The p-v amplitude responses at the frequencies of 0.67 Hz, 1 Hz, 2 Hz, 10 Hz, 20 Hz, 40 Hz are between 70 % and 140 % of the response at 5 Hz.*

If the manufacturer claims that the EQUIPMENT is capable of recording ECGs from infants weighing less than 10 kg, replace the upper test frequency of 40 Hz by 55 Hz.